EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

LIFE TECHNOLOGIES)(
CORPORATION, ET AL.,)(CIVIL DOCKET NO.
)(2:09-CV-283-TJW-CE
VS.)(MARSHALL, TEXAS
)(
BIOSEARCH TECHNOLOGIES,)(AUGUST 23, 2011
INC.)(9:00 A.M.

CLAIM CONSTRUCTION HEARING
BEFORE THE HONORABLE JUDGE CHAD EVERINGHAM
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

FOR THE PLAINTIFFS: (See Attorney Sign-In Sheet)

FOR THE DEFENDANTS: (See Attorney Sign-In Sheet)

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(Proceedings recorded by mechanical stenography, transcript produced on a CAT system.)

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August 23, 2011

LAW CLERK: All rise.
THE COURT: Please be seated.
All right. Good morning.
MR. JOHNSON: Morning.
MR. MALONEY: Morning, Your Honor.
THE COURT: We have a Markman hearing in Life Technologies against Biosearch and others. It's Case 2:09-CV-283.
What says the Plaintiff?
MR. MALONEY: Your Honor, Colin Maloney, here with Cora Schmid and Emanuel Vacchiano. We're here ready to proceed, Your Honor, for the Plaintiff.
THE COURT: Good morning.
For the Defendant?
MR. HAWES: Morning, Your Honor. Erik Hawes, Morgan, Lewis and Bockius. I'm here with Dan Johnson and Rita Tautkus. We're ready to proceed, Your Honor.
THE COURT: Good morning.
MR. JOHNSON: Good morning.
THE COURT: All right. I've set aside an hour and a half per side for argument. I've looked at the briefing and the tutorials. I'm fairly familiar with the actual disputes.
So, Mr. Maloney, I think you know the rule

on opening. You need to use at least half of your time in your opening presentation, otherwise, you're limited to a reduced amount of time for rebuttal.
MR. MALONEY: Thank you, Your Honor.
THE COURT: With that, you may proceed.
MR. MALONEY: Thank you. Ms. Schmid is going to give our presentation, Your Honor.
THE COURT: All right. Ms. Schmid.
MS. SCHMID: Good morning, Your Honor.
THE COURT: Morning.
MS. SCHMID: I'm Cora Schmid from Life Technologies here on behalf of Plaintiffs, Life Technologies and Applied Biosystems.
As Your Honor saw in the briefing, Plaintiffs are asserting five patents in this case, which are a family of patents that we refer to as the Livak patents for the primary inventor, Dr. Kenneth Livak.
The first patent in this family is what we call the '848 patent. As all of the other four patents claim priority to the '848 patent, we'll be citing to the specification of the '848 patent, and all the citations to the specification of the '848 patent include all five of the patents.
Likewise, the other four patents are all

continuations-in-part of the '848 patent and share essentially identical specifications. So citations to the '591 patent, for simplicity, will be used to reference the specifications of all four of those patents.

We're going to be talking about three categories of claim terms. The first three terms that we're going to be discussing include clear definitions of the terms in the specifications, and the Court should adopt those definitions as the construction.

In the second category, terms four and five, the claims do not require construction and Defendants show this by using the very words of the claim term in their proposed construction.

Finally, the last three terms, terms six, seven, and eight, Defendants argue are means-plus-function terms, however, these terms don't use the word means, which creates a strong presumption that they're not means-plus-function, and in addition, all three of those disclose a clear structure, oligonucleotide sequences or oligonucleotide probes, and so are not means-plus-function. They're also not indefinite and do not require construction.

We'll now go through each of these terms in these categories. As I mentioned, the first category or

the first three terms in which the patentee defined the term in the specification. Quick review of the law, Phillips has made clear that -- that a claim term is generally given its plain and ordinary meaning or its ordinary and customary meaning, however, the patentee can act as their own lexicographer, and that is, they can give a term a special definition as long as it's clear in the specification, and when that happens, the Court should use that definition as the claim construction. Indeed, the specification has been recognized as the single best guide to the meaning of a disputed term.

Now, the first term that we're going to talk about today is quencher molecule. The basic dispute between the parties is whether or not quencher molecules that emit light, that is, quencher molecules that are called fluorescent are going to be excluded from the word quencher molecule.

Now, if we look at the specification, the specification is clear that the definition of quencher molecule should be broader than that. Specifically, the mol -- the definition is the term that Plaintiffs propose, and it's def -- it is defined in terms of absorbing fluorescent energy and quenching a florescent signal. It's not defined in terms of what it does with

that energy, that is, whether it fluoresces the energy and emits it as light or whether it dissipates it in a different way.

This -- while a patentee can act as their own lexicographer and give a word a special definition, in this case, all the patentees have done is made clear what the plain and ordinary meaning of the word is, which Defendants have recognized.

In the tutorial they submitted to this Court, they showed two kinds of quenchers, a quencher that is a fluorescent quencher, which absorbs the light from a reporter molecule over here and emits it as lights or fluorescence, and quenchers that they call dark quenchers, which absorb the light from a reporter but do not emit it as light.

And as you can see right there, they even specifically call this type of molecule a quencher under it's plain and ordinary meaning, just a dark quencher instead of a fluorescent quencher.

Now, the intrinsic evidence is just riddled with examples that quencher molecule is broad enough to include both fluorescent and nonfluorescent quencher molecules. If you look at the words of the claims themselves, you can see that sometimes the patentee describes a quencher molecule and sometimes they

describe a fluorescent quencher molecule.

Now, just as the en banc Federal Circuit in Phillips found that steel baffles means baffles that are not necessarily made of steel -- I'm sorry, I misspoke. It says that steel baffles means that baffles inherently are not necessarily made of steel. Likewise, here the fact that the patentees talked about a fluorescent quencher means that quencher molecules are not necessarily fluorescent.

Similarly, the specification explicitly states that quenchers can either dissipate the energy it absorbed nonradiatively, or it can emit it at light. However, Defendants are arguing that it must be required to emit light.

Again, the specification shows in another location, it talks about nonfluorescent quencher molecules. It refers to them as chromogenic molecules -- chromogenic molecules. In light of the overwhelming intrinsic evidence, this is a simple task. The word quencher means what it means. It means a molecule that absorbs light from a reporter and then can either emit that light as fluorescence, or it can dissipate it nonradiatively.

What Defendants are doing are asking the Court to rewrite the claims to say that quencher means

something it doesn't mean. But the Federal Circuit is clear, the Court --

THE COURT: Well, aren't they saying that the patentee sort of at least implied that the quencher molecules have to -- have to emit light --

MS. SCHMID: They're saying that --

THE COURT: -- by virtue of the comparison between the fluorescence of the reporter and the quencher?

MS. SCHMID: So using their mathematical formulas, they're arguing that certain of the claims would be -- would not make sense if a fluorescent --

THE COURT: Tell me why they would make sense.

MS. SCHMID: Excuse me?

THE COURT: Tell me why they would make sense.

MS. SCHMID: They would make sense because the very term that they point to, that term itself limits that particular claim to a nonfluorescent quencher. However, it doesn't apply to all the other claims.

Specifically, by having a ratio with a non -- with -- with a quencher -- with the fluorescence emitted from a quencher on the bottom, it's that very

requirement that there is fluorescence from a quencher that adds an additional limitation to that particular claim that's not attached just to the word quencher. It's attached to the location of the quencher on the bottom of a fraction.

THE COURT: Well, are you telling me that under those circumstances where a comparison or a ratio is required that the quencher molecule in those claims is necessarily one that is a fluorescent quencher?

MS. SCHMID: Correct.

THE COURT: Okay.

MS. SCHMID: Plaintiffs believe the Court should adopt the clear definition given in the specification which is supported by the intrinsic evidence and also reflects the plain and ordinary meaning of the word quencher.

Moving on to the second term, a hairpin structure. Both the parties agree that a hairpin structure is a strand -- is when a strand of DNA loops back and hybridizes with itself when certain basepairs in different parts of the strand form bonds with each other.

What the parties disagree about is what other requirements should be included in the definition,

and most particularly, whether or not the definition should relate to the relationship of the reporter and quencher.

Now, the patentees gave a definition of hairpin structure in the specification. This is -- oh, I'm sorry, this is a clear definition essentially saying this is what hairpin structure means. In case there's any ambiguity in the prosecution history, the patentees represented that this very definition clearly defines what is intended by hairpin structure.

Now, Defendants express some concern that this is not the plain and ordinary meaning that just an average biologist on the street would give to hairpin structure, but there's two problems with this. First of all, as we've discussed, Phillips says that a patentee can act as their own lexicographer and give a word a special definition, but what's further, the definition that -- that the patentees have used in this case is a definition that other people use in this exact field of this type of probe. For example, one of the Defendants in this case, Biosearch Technologies, has used the exact definition in some of its own patents.

Further, this was not an accident that this definition was used. This definition was specifically used to distinguish over prior art in that there were

pieces of prior art, such as Bagwell, that taught the use of a hairpin structure for the purpose of bringing a reporter and quencher molecule next to each other.

Plaintiffs are proposing one clarification to the term from the specification. Particularly, Plaintiffs are concerned that "proximity with" might be confusing to a lay jury and propose clarifying this with the slight phrase "next to." The reasons for this clarification are based on the --

THE COURT: How about "nearby"?

MS. SCHMID: Yeah.

THE COURT: I mean, "proximity with" seems to be -- to mean more than "next to" is what I'm -- what I'm driving at.

MS. SCHMID: Uh-huh.

THE COURT: And I think the argument that was made by the Defendants was that that was a more restrictive definition than even what was found in the patent. So if --

MS. SCHMID: We certainly are amenable to other words to express the same concepts. The concept that we're trying to -- to get across is sort of looking at the prior art. I guess to put it in context, we believe that the reason the Defendants are fighting so hard to keep the relationship between the reporter and

the quencher out is because probes will periodically -- just certain bases somewhere on the probe might happen to be complimentary, but it's not going to impact the reporter and quencher.

But the -- the probes that the patentees were distinguishing over very specifically were designed to have this stretch of -- of complimentary basepairs specifically for the purpose of bringing the reporter and quencher next to each other.

So certainly if -- if the Court feels a different word would better express this, we would be fine with that. But we do believe that it's very clear from the intrinsic record that this is the prior art that led to this limitation, and that is what should be reflected.

So here's one example, whereas said hybridization is forming, here's the loop where it loops back on itself, and the reporter and quencher are brought next to each other. A second example, again, you have hybridization, a loop, and the reporter and quencher brought next to each other.

Coming from the notice of allowability, the examiner -- another word that Defendants (sic) would be amenable to is "together," which is the word that the patent examiner used. The patent examiner specifically

noted that the closest prior art included Bagwell, et al, and that Bagwell was distinguishable because it taught a probe designed to form a hairpin that is -- when it is not hybridized to the target molecule as a means of bringing the reporter and quencher molecules together. So Defendants (sic) would also be amenable to the word "together."

THE COURT: You mean Plaintiff?

MS. SCHMID: I'm so sorry, the Plaintiffs --

THE COURT: It's all right.

MS. SCHMID: -- would also be amenable to the words "together." You would have to ask the Defendants what they would --

THE COURT: I suspect --

MS. SCHMID: -- be amenable to.

THE COURT: -- I'll hear a disagreement about that.

MR. JOHNSON: That's a fair assumption, Your Honor.

THE COURT: I don't want to get ahead of myself.

MS. SCHMID: The word "next to," there's support for that from the extrinsic record, Webster's Dictionary at the time.

Now, Defendant's construction cannot be

correct because it would read a preferred embodiment out of the specification. Just to walk through to make sure this is clear, one of the embodiments disclosed in the '848 and other patents is what's called the P2 probe. You can see, so the reporter and quencher are attached to the end Ts. You can see the sequences is TCGCA.

So then the examiner in an interview looked at this probe and thought it would form a structure, an examiner -- it's in the examiner's handwriting. They wrote it out, you know, TCGC, just like up here, and they noted, look, here's the probe. It will go along, and then suddenly it will loop back, and this A might bind with this T. These two would not be complimentary, but this one is complimentary, this pair is complimentary, this pair is complimentary, this pair is complimentary. Oh, look, there's four complimentary basepairs that are contiguous.

So under Defendant's construction, this would be a hairpin. Under Plaintiffs', it would not, because the reporter and quencher on those two Ts, they would not be brought together. So -- and Defendants have admitted that under their construction this would form a hairpin.

So why is this relevant? Because the claims include hairpin as a negative limitation, that is, they

claim probes which do not hybridize to form a hairpin. So, in other words, they claim probes that would not do this, but this probe is a preferred embodiment. And as the Federal Circuit has made clear, terms -- claim constructions that exclude preferred embodiments from the scope of the patent claim, not from the scope of the term, but from the scope -- scope of the patent claim are strongly disfavored.

For these reasons, Plaintiffs propose that the Court adopt the definition given by the patentees in the specification with the clarification of "next to" or another word that the Court prefers that expresses the same concept -- expresses the proper concept with for "proximity with" that the patentees and examiner were discussing in the intrinsic record.

The third term involves separation between a reporter and quencher molecule. The dispute here is what part of the specification to look at. Do we look at the part of the specification that uses the word separation, which is the same word used in the claim term, or do we look at parts of the specification that talk about nucleotide positioning and naming?

Now, one quick notation, this underlining, this is something that I -- I believe both the parties will be using, that essentially means the term appears

in slightly different formats.
THE COURT: Yeah.
MS. SCHMID: Okay. Now, the part of the specification that talks about separation, the word used in the claim, defines that a separation of about 6 to 16 nucleotides is achieved by attaching one member of a reporter pair to a five prime end of a probe and the other member to a base 16 -- 6 to 16 nucleotides away. So when it says, away, grammatically what it's referring back to is the five prime end of the probe.
So what is a five prime end of a probe? When the claims talk about ends of probes, they're talking about the terminal nucleotides of a probe, and that's consistent with the Defendant's understanding, what they presented in their tutorial to this Court, where they show a reporter and a quencher both attached to the end of a probe right here at the terminal nucleotide.
So what this slide is saying is this separation is achieved by attaching, for example, a reporter to the five prime nucleotide of the probe and the other member to a nucleotide 6 to 16 nucleotides away from that first nucleotide.
What does this look like in practice? The patentee showed us in the prosecution history. They

characterize a reference, Lee, et al, and explain that in this reference, the reporter and quencher, the quencher here is called an accepter, are separated by seven nucleotides.
So you can see here is the reporter. It's attached to the five prime terminal nucleotide, and then counting one, two, three, four, five, six, seven away, the quencher is attached. Likewise, below it, the reporter is attached to this terminal nucleotide, and then one, two, three, four, five, six, seven away from that five prime nucleotide, the quencher is attached.
Defendants have not denied that this is what it teaches in the prosecution history.
Now, Defendants also point to the specification, but the point -- the part of the specification they point to doesn't use the word separated or separation, which is the word of the claim. Instead, it talks about naming and it talks about nucleotide position. They give no reason for why a patentee might not choose to act as a lexicographer for a different word separate -- separation and use separation notation for both.
For these reasons, Plaintiffs believe the Court should adopt the definition given in the specification for separation, which is supported by the

prosecution history.
So those are the first three claims, all of which the patentee defined in the specification.
We're now going to talk about the next two claims which do not require construction.
As a reminder, the Federal Circuit has emphasized that a term does not need to be construed just because one party asked for it to be construed, but rather it should be construed where there -- the meanings would need clarification or where construction is necessary to aid in the determination of infringement or invalidity.
If we look at term four, terminal nucleotide, the Defendants have used the word terminal nucleotide in their proposed construction admitting that the words themselves, terminal and nucleotide, will not be confusing to a jury.
Further, they have not identified any concrete dispute related to invalidity or infringement that requires construction of this term. They have generally stated that there -- there is a dispute but refused to identify what it is. So either they're asking this Court for an advisory opinion, or they're intentionally hiding the ball and refusing to identify why there's a dispute about this term.

Further, the -- if the Court should decide to construe terminal nucleotide, it should do so with the plain and ordinary meaning, which is shown by looking through the intrinsic record as the end monomer of an oligonucleotide. We say this because when terminal nucleotides are discussed --
THE COURT: You may want to slow down a little bit with the --
MS. SCHMID: Oh, I'm sorry.
THE COURT: -- the nucleotide terms.
MS. SCHMID: Big words.
THE COURT: She's -- well, she's trying to keep up.
MS. SCHMID: Definitely, please, if I talk to fast again, yell at me.
So the claims show that when the patentees discussed terminal nucleotides, they're talking about a nucleotide on the end of the probe, which the probe relates to an oligonucleotide probe, and in the specification, it shows that probes are oligonucleotide probes.
And the parties have agreed on language that was taken from a definition in the specification that an oligonucleotide is a linear array of monomers. So putting this together, a terminal nucleotide would be

the last of these monomers on the line, so the end monomer of an oligonucleotide.

Over all, though, Plaintiffs believe that no construction of this term is necessary because Defendants used the very word of the term in their construction, and they have not identified any dispute relevant to this term.

The next term at issue is monitoring the fluorescence. The dispute between the parties first is should this claim be construed at all, and if so, should the Court add limitations to the plain and ordinary meaning?

Defendants are proposing adding two limitations. Note -- it's worth noting they, again, use the exact same language, recognizing that a jury will understand what monitoring means and a jury will understand what fluorescence means.

But what they want to add is that the monitoring has to happen at a particular wavelength, and, also, they want to add that you can't start monitoring until the reaction is done.

Now, for the first limitation that the monitoring has to happen at a particular wavelength, this is contradicted by the specification. The specification shows an example that monitors at two

wavelengths, 518 and 5 -- and 582. Plaintiffs pointed this out in their opening brief, and Defendants did not deny that this is disclosed in the specification.

Similarly, Defendant's second proposed limitation that you have to wait until a reaction is over before you can start monitoring it is also contradicted by the intrinsic record. Specifically, the specification that the patents cite to a reference by Higuchi, et al, which was published in 1992, that's two years before the first patent in this family was filed, and this reference discusses continuous monitoring of PCR, and it just describes taking an off-the-shelf fiberoptic device and using that to monitor the fluorescence throughout the reaction.

The specification also cites to another reference, also by Higuchi, et al, this one published in 1993, one year before the filing of the first patent-in-suit, which also describes continuous monitoring of fluorescence, this time using an off-the-shelf video camera.

Now, in order to deny that fluorescence monitoring was done, Defendants try to mischaracterize some extrinsic references. Specifically, they look to some marketing materials published after the patents that talk about -- that discuss monitoring. And they

take some words out of context, when what this -- what these articles are really talking about, you know, one of them is -- is marketing material and may include some words about the importance that -- the marketing materials may include some words that seem a little bit like hyperbole, but that kind of language --

THE COURT: In marketing materials? You're kidding me.

MS. SCHMID: That kind of language is common in marketing materials.

And, likewise, they cite a scientific paper which discusses the introduction of a new machine, and what was really important in this machine, the goal was to develop high-throughput methodology for doing this. So they weren't saying that before 1996, no one had done this before. They were saying their goal was to come up with something high-throughput, and that their machine allows you to do 96 samples at the same time.

So Higuchi, et al, were sitting there, you know, with their little fiberoptics and their video cameras, and they could do a couple of samples, but now this new machine launched by Applied Biosystems allows 96 wells at the same time.

Now, if the Court does believe the term needs construction, Plaintiffs believe the Court should

adopt the plain and ordinary meaning, which is checking on the fluorescence during the reaction. This is supported by the intrinsic record which shows real-time monitoring of an amplification reaction and that monitoring was happening during the reaction.

So in summary, Plaintiffs believe that no construction is required. The Defendants used the words of the terms in their constructions, and the -- their proposed limitations are contradicted by the intrinsic record.

Moving on to the last three terms at issue here, terms six through eight, Defendants argue that these terms are means-plus-function terms, however, they're not.

As a quick review of means-plus-function law, the Federal Circuit has made clear that if the word means is not present, there is a strong presumption that's not readily overcome that the claims are not means-plus-function.

In order to overcome this presumption, they -- Defendants essentially need to show that the claim is completely lacking in structure. As the Federal Circuit said in the Lighting World case, it is sufficient for us, the Plaintiffs, if the claim term is used in common parlance or by persons of skill in the

pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies structures by their function.

Now, this Lighting World case is an important case. In this case, the Defendants that argued that a term was means-plus-function, they even submitted an expert declaration claiming that the word had no specific structure, and the Court -- the Federal Circuit overturned the district court's ruling that this was a means-plus-function term holding that even with an expert declaration, the expert had used the wrong standard because the expert was looking for one specific concrete structure when really a broad class of structures is fine as long as persons of skill in the pertinent art would recognize it as a structure.

So as the Court said in Phillips, means-plus-function claiming applies only to purely functional limitations.

So some examples of limitations that the Federal Circuit has found do not invoke means-plus-function include aesthetic correction circuitry, connector assembly, reciprocating member, detent mechanism.

Looking at the -- the term at issue here, this claim term is not means-plus-function because it

designates a specific structure, oligonucleotide probe or oligonucleotide sequence. Now, these two words are used interchangeably by those of skill in the art, oligonucleotide sequence and oligonucleotide probe.

Now, how do we know it's a structure? First, we know because Defendants agreed to a definition of oligonucleotide that was given by the specif -- by the patentees in the specification, and in this definition, it's a structure. It's a linear oligomer of natural or modified monomers or linkages. We also know because it says so in the specification. Oligonucleotide probes of the invention can be synthesized by a number of approaches. So this is something that can be made. It's not some theoretical etherial means of creating fluorescence.

We also know because Defendants showed in their tutorial this is a probe. It has a structure. You can see it. This is the probe in one confirmation. It changes confirmation, but it's the same structure.

And, again, just to highlight, the Court this time in Crane has said, the fact that a term is broad and might include almost an infinite number of structures did not render the limitation means-plus-function.

This is important because Plaintiffs have

not been able to cite to any case that discusses oligonucleotide sequence, probes, DNA, RNA, that says that they're actually means-plus-function. So instead, they try to argue that because the sequence of an oligonucleotide can be different, it can't be a structure because there could be so many different possible structures, which is why it's so important that even an infinite number of structures...

So to think about it another way, in the CCS case, the Court found that reciprocating member was not means-plus-function. Now, reciprocating member, those -- you know, it's well known in the art what a reciprocating member is, but they can still come in all sizes. You know, you can imagine if you're just going up and down tiny, tiny amounts, there could be an almost infinite number of sizes. Yet still, they say one of skill in the art can pick out the right size, figure out what's going to work, and make it work.

Now, because there's no case -- case law supporting them, additionally, really the only evidence that they're saying this is not a structure is attorney argument. They haven't brought forward any expert declarations claiming that one of skill in the art would not know what an oligonucleotide probe is.

So instead, they rely entirely on one case

from the District of Delaware which differs from this case. This case talks about a type of circuit. I believe it's a soft-something circuit. I'm blanking on the other word, but in this Court -- in this case, even in this case, it particularly distinguishes its own case from the Federal Circuit case of Linear, because in Linear, circuit was found not to be means-plus-function because it was sufficiently coupled with a description of the circuit's operation.

Likewise, in this case, not only is oligonucleotide probe or oligonucleotide sequence a sufficient structure on its own, the term also includes other language that's description of the probe.

Finally, other cases in addition to Linear employ the same reasoning, that the claim language here is -- does not merely describe a circuit. It adds further structure by describing the operation of the circuit, which is exactly what's happening in these terms. They provide further description about the operation of the probe.

Plaintiffs' next -- the next term to be construed -- or I guess in summary, first, the term we're looking at, the said oligonucleotide term, term six, it's not means-plus-function because it lacks the words means creating a strong presumption that it's not

means-plus-function, and it also includes specific structures of oligonucleotide probe and oligonucleotide sequence.

The next term is similar. It's a long term. Defendants are arguing that it's means-plus-function. In the alternative, they're arguing that it's too indefinite or ambiguous to interpret. And, finally, a second alternative, they propose a specific construction in which they propose importing limitations from a single example.

None of these approaches should be adopted.

Just as with the previous term, this term has a structure, and you can see the structure right here. It's oligonucleotide sequence, and we know that oligonucleotides are -- oligonucleotide sequences are structures for all of the same reasons we discussed. We also know that the term is not indefinite because Defendants did not contest that optimization was well known in the art at the time these patents were filed.

Additionally, the law is that a claim cannot be indefinite if the meaning of the claim is discernible even if it would be difficult to come up with a meaning for it. Now, Defendants can't have it both ways. They're trying to say it's indefinite, but then they're also proposing a construction. So it's got to be one or

the other, and by admitting that there's a possible construction for it, Defendants are showing that the claim term is not indefinite.

However, the ultimate construction that Defendants are proposing imports the limitations from one particular example which Phillips has said clearly you cannot do. So in sum, this term is not means-plus-function because it lacks the word means and because it includes specific structures. It's not indefinite, and it also -- Defendant's proposed construction improperly imports limitations from a single example, should be rejected, and no construction is required because Defendants have not identified any words in this claim that -- that they consider confusing or that a lay jury would not understand.

The last term is very similar. Defendants are, again, arguing that this term should be means-plus-function. In the alternative, that it's indefinite or in the second alternative that it should have one particular construction that imports limitations from a single example.

Just as before, though, this term also includes structures of -- lower down -- the probe and the oligonucleotide sequence. But both oligonucleotide probes and oligonucleotide sequences are well known

structures in the art. The term is not indefinite because Defendants have not disputed that optimization was well known in the art at the time the patents were filed and because the standard for indefiniteness is higher than Defendants have met, and, finally, because their construction is improper because it improperly is importing limitations in from a single example.

So we covered a lot. So as a quick review, the first three terms should be construed as the patents defined them in the specification. The second terms do not require construction because the patentees admit this by using the very terms in the definition. And the final terms are not means-plus-function because they do not include the word means because they disclose structures, they are not indefinite, and they do not require construction.

THE COURT: How would one of skill in the art go about measuring the ratio of the fluorescence's intensities as called out in, say, the last term?

MS. SCHMID: In -- so the measurement of fluorescence is something that was well known in the art. You know, in addition to the examples provided in the patent, the example cited in the intrinsic record, including the Higuchi paper, disclosed measuring of fluorescence, and then once fluorescence is measured,

the comparison of whether or not it's six times greater is even -- I believe table -- it's disclosed in the patent specification. I don't have the exact table in front of me, but when you have two numbers just comparing them to see if they're six times greater or not.

THE COURT: Well, I think their argument, though, as I understood it, was that that ratio depends on the conditions under which you're measuring the -- the fluorescence, correct?

MS. SCHMID: Correct.

THE COURT: So if I alter the solution that I'm examining for taking measurements and make the ratio not six times, have I -- do I infringe or not?

MS. SCHMID: So as described, for the indefiniteness argument, optimization of reaction conditions was well known in the art. People running these PCR reactions knew all the different variables and conditions and knew how to optimize them.

In fact, the very figure that Defendants show where they show the impact of magnesium and how it can change and impact figures, that shows how those of skill in the art knew how to test and optimize different conditions.

THE COURT: Okay.

MS. SCHMID: So what one of skill in the art would have understood the patent to be saying is optimize a reaction, then you take the fluorescence in that reaction, you got another reaction, optimize that reaction, take the fluorescence in that reaction, compare the fluorescence of the two and see whether it's six volts higher or not.

THE COURT: So is the answer to my question, yes, it would infringe, or, no, it would not infringe if I was able to alter the properties of the solution such that the ratio was not at least six times as called out in the claim?

MS. SCHMID: No, it would not infringe.

THE COURT: Okay. All right.

MS. SCHMID: And if there are no further questions, I reserve time for rebuttal.

THE COURT: Thank you.

MR. JOHNSON: Morning, Your Honor.

THE COURT: Good morning.

MR. JOHNSON: I think we've got ours. I'm going to move through some of these fairly quickly since the overview is already done, and I don't want to waste your time. So --

THE COURT: I mean, you take what time you need.

MR. JOHNSON: I understand. I understand.

THE COURT: You're not -- you're not wasting my time.

MR. JOHNSON: All right. So we've already gone through and talked about the basic DNA structures. You're familiar with that. And we've talked about FRET, which you're also familiar with, and DNA detection, which we've already gone through.

So if we go over to our summary, and obviously we have a very different view of what constitutes monitoring of fluorescence, we don't think it is, quote -- there was a, quote, optimization that was new -- that was understood. We think that the patent has very specific requirements for determining fluorescence which cannot be simply ignored.

The same is true with quencher molecule and how it's supposedly defined. We think that the quencher molecule that they, in fact, are claiming is one that requires fluorescence, and we'll point out to the Court why we believe that to be the case.

Let's go to the next slide.

This hairpin structure, the critical point to be made on hairpin structure is they are defining hairpin structure as a probe, and it -- and the patent makes it clear that it's not a probe, that you don't

have a reporter and you don't have a quencher. You have a particular structure which we will discuss. And that's why there's this dispute between the parties because they're using language that talks about a probe when they very clearly told the Patent Office it was not.

The issue of separation of reporter and quencher we're going to discuss. Also, why we think the term terminal nucleotide has to be defined. And then we're going to go through this ratio issue, again, for the Court because we think it is -- it is going to be critical to the understanding of the issues the jury's going to have to decide.

Next slide.

Again, abbreviation of what is an -- is existing is something we're -- we think the Court needs to focus on for purposes of claim construction.

And so let's start with monitoring of fluorescence. So -- and, oh, by the way, I do apologize. I didn't say, I'm -- I'm Dan Johnson, and I'm here on behalf of Biosearch.

So when we're talking about monitoring the fluorescence, while the other side says it doesn't require any interpretation, we say that monitoring the generation of fluorescence at a particular wavelength

only at the conclusion of an amplification reaction. Why is that? That's because of the state of the art that existed as of the time this patent was filed for.

And we cite the PC Connector case, as well as Phillips, for the proposition you can't claim the existence of an invention when a portion of what you are claiming was not invented yet. You have to show -- you have to be limited to what was the testing being done at the time.

THE COURT: Didn't PC Connector have in the claim language itself a temporal limitation to contemporary or existing technologies?

MR. JOHNSON: That's true, it did. However, in this -- we -- we actually have the same thing in the situation before this Court, and it's found in their example in the -- it's in all of the patents, but we can look specifically at the -- the '591. So, for example, let's go to the next -- next slide, we talk about -- back up for a second. One slide before.

In their example -- in the -- in the patent itself, they talk about the desirability of this real-time PCR, and you say, okay, well, that's -- that would suggest that this is something we'd like to do, but -- so what you have to do is look at, in fact, what they did.

If we go to the next slide, here's what we're talking about. They actually have a specific recipe for how you go about this monitoring, and it required specific equipment. Whether you have that specific equipment or not is not important. But they had two target genes they were using. They had a specific recipe, which included magnesium concentration. And I know you just heard everybody knew how to optimize. Well, I fundamentally disagree with that. If they knew how to optimize, there would be no need for this patent and there would be no need for all the research that was being done trying to figure out how you could get these probes to work in the proper fashion.

They also had specific target sequences closed -- disclosed. They gave you specific times and specific temperatures you had to do certain acts. And, finally, they had to tell -- they told you and disclosed when this monitoring was to be done.

And if we go to the next slide, Your Honor, if you go to Column 19 of the '591, you find their, quote, method for monitoring PCR amplification. I know you just heard that there -- that these shouldn't be means-plus-function, but here is exactly what they told -- told you to do. And they didn't have any other

examples.

In that method, they I told you what the target gene was. They told you the specific magnesium concentration. And we pointed out why that's so important because you -- the results will change radically depending upon that magnesium concentration. It's also going to change based upon the cycle time.

Go to the next slide.

And over here we have the second gene, and you'll see a different magnesium concen -- concentration, a different cycle time. And this is important because if you were somebody of ordinary skill in the art, you'd have to know this recipe, otherwise, you're just experimenting.

And therein lies their problem. They want to say it's obvious or it's clear, but in order to do this analysis -- and then what's the analysis? To figure out the fluorescence so that you can determine if the probe is successful or not, you have to go through these steps.

The next slide, please.

So we talked about -- you heard them talk to you about the issue of end time analysis as opposed to real-time, this is what they disclosed. They disclosed for amplification reaction 40 milliliters was

transferred to an individual well. That means it was at the end. You put it in a separate machine of a white 96-well microtiter plate, and then fluorescence was measured. That's end time PCR. Their end time analysis, that is the only disclosure in this patent that tells one of ordinary skill in the art how to do what they are claiming.

Now, they would say, well, that's just one example. That's the only example. There is no disclosure of how to do anything approaching real-time PCR in this patent. And the reason this is important, and it goes to this whole ratio issue, because they, in effect, have laid out exactly how you were supposed to do the -- the analysis, and that is contained in their patent. They don't -- and they would like to expand it to include real-time so they can ensnare future technology. But this is what they disclosed.

Now, the language --

THE COURT: But is it a claim construction question, or is it a written description issue?

MR. JOHNSON: You know, I have to tell you the truth, I battled that issue. We have argued --

THE COURT: Me too.

MR. JOHNSON: We have argued over that. I can tell you that my view of the world is that it's

both, and the reason it's both is because of the way they drafted the language.

Now, you know, obviously, you know where we're -- we're going to end up filing a motion for summary judgment at some point, but I think it's claim construction because monitoring, if it meant any type of monitoring, would necessarily imply that all aspects of monitoring were known to somebody of ordinary skill in the art, and what we're saying is, you very clearly understood what monitoring was, you disclosed it, and it was end point monitoring.

THE COURT: Well, what's your answer to their references that were incorporated?

MR. JOHNSON: The references that were incorporated discussed the concept of doing real-time monitoring, but there was nothing in the patent or even in the references they cited that showed you this was the way one would do it. That was a suggestion of how one might do real-time PCR. That's fundamentally different.

And as we point out in our papers, their claim that it was known is rebutted by the fact that nobody did it. And that if they, in fact, had believed there was a way to do it, instead of using the words like desirable, they would have -- just like they did

with their recipe for the end point, they would have given us a recipe, but no such recipe was given. And we are convinced that a recipe was critical in this case because we're not talking about opening up a can of soup here. We're testing for probes to determine genetic makeup and genetic issues. That could not be done just simply by anybody walking down the street.

The next slide.

The -- the argument they make about, well, we could do it 96 times, and so, therefore, this was a different probe, if you go back two slides -- go back two slides to the quote that I gave you -- there's a 96 well microtiter plate that they had disclosed. So that obviously was not the differentiator. It wasn't 96. It was the difference between end point and real-time.

Go back -- go forward, please.

Now, we discussed the Higuchi reference and why there is no disclosure at that point to establish what ultimately became real-time PCR. We believe there's -- their subsequent statements that, in fact, they invented it years later is, in fact, correct, but that in any event, they were obligated to disclose to someone of ordinary skill in the art how to accomplish this particular result, and they did not.

Next.

All right. Quencher molecules, the Court -- I heard the admission that they concede that at least as to certain claims, the fluorescence is required because, obviously, if you get to 0, you get a nonsensical result. I'm not going to belabor the point other than to say that as far as we're concerned, that's the only result they can get, and the reason is because they are measuring fluorescence -- in those instances where they're measuring the fluorescence between the quencher and the reporter, it has to be done in a certain way. And why is that important? It's important because --

Let's go to the next slide -- in the -- one more slide, please, keep going.

In their file wrapper, they said in one of their earlier -- earlier proposals that this quencher, all it had to do was, quote -- quote, substantially quench. That's in the wrapper in their original claim for the -- original Claim 1, and that's at Exhibit U. The examiner rejected it saying, wait a second, substantially, under 35 U.S.C. 112, is indefinite because it does not allow to determine the metes and bounds of the invention.

Now, if substantially quenches doesn't do it, they removed it and put it in quenching, they didn't ask for total quenched or completely quenched, it is

some form of quenching, which as I understand it, would still result in a finding that there had to be some fluorescence, because, otherwise, they would have, in effect, invented what became known as the dark quencher, and they never say that -- they never used the word substantially because they gave it up, and they never used the words totally because they never claim it.

Our view of the world is this is the best evidence that we were right when we said looking at the formula, fluorescence greater than 0 is required.

Next slide.

And we've gone through the analysis. You can't have -- you can't get to this greater than six number without having the ability to do a calculation. And doing that greater than six calculation requires you to look at the ratio of the various -- of the fluorescence, and you can't have 0 in the denominator.

Now, they say, well, we're trying to rewrite the claim. We're not. We're saying, you knew you couldn't get substantially quenched, so when you went to quenched, you necessarily ended up in a situation where you could not end up with a quencher that did not emit any light whatsoever.

Next slide. Next slide. Next Slide.

Hairpin structure. Now, hairpin structure

is interesting, Your Honor. We call it a single stranded oligonucleotide sequence that is hybridized with itself to form a double stranded duplex of three or more contiguous basepairs at the detection temperature of the assay.

Now, the Plaintiffs' proposal, and they quote from the patent, and this is very important, what they did was they quoted from a reference to prior art in the patent, and it says, where the probe hybridizes to itself to form a loop. Now, so you see their language, it was a probe that was hybridizing to itself. Obviously, then the -- with the reporter and the quencher molecule close together, and then they said, next to. Let me show you what they said in the file wrapper.

Can you guys throw that up?

Let me just put it on the ELMO.

This is their Exhibit G, Your Honor. Let me see if I can get it big enough so you can see it.

THE COURT: It's their Exhibit G?

MR. JOHNSON: Their Exhibit G. They specifically say, it is clear that applicants intended probes which do not hybridize with themselves to form a hairpin structure to fall within the scope of the present invention. They go on to say -- and that's at

Page 3, Your Honor, of Exhibit G.

THE COURT: I'm with you.

MR. JOHNSON: And you keep going, it says, the intention of applicants to exclude probes which are designed to form hairpin structures is made clear by applicants teaching away from the use of probes with a hairpin structure. And the reason they taught away from it is because it -- it had some inherent deficiencies. Specifically, the specification teaches that probes, including hairpin structure, had the disadvantage that they can be difficult to design and may interfere with the hybridization of the probe to the target sequence.

And if you go over to the next page, you'll see the following language. In view of the various teachings in the specification, applicants maintain that clear support is provided for the phrase, an oligonucleotide sequence which does not hybridize with itself to form a hairpin structure, and respectfully requests that the examiner withdraw the present rejection under 35 U.S.C. 112, first paragraph.

Well, you can't come -- you can't tell the examiner, our hairpin structure did not include probes. We taught away from probes, and we defined it exactly the way the Defendants have defined it, save and except for I'm going to talk about the double stranded duplex

of three or more contiguous pairs, because they can't claim a probe as being a hairpin. They gave that away.

Now, the question is proximity is not the same as next to. And you're absolutely right. Prox -- words like proximity, nearby, make a lot of sense in connection with the -- the probes we're talking about.

They're going to beat me up, but I apologize. Go back to the language -- go back and show me the slides where we have the DNA examples right at the beginning.

Okay. Let's go -- keep -- flip it forward.

You see, this is an example, Your Honor, of a hairpin structure. Two things to point out. Number one, the base or the stem, they are proximately nearby, but that's not necessarily next to or touching. Why that's important has to do with this.

If I can walk over, I can explain a little better.

Basically, if you view this as a balloon where you've got a string at the bottom, that string is the stem. If the stem is too small, you don't end up with a hairpin, you end up basically with a circle, and it has certain implications for the performance. So you've got to have a big enough base or a long enough base to make it work.

When we looked at all of the examples in the patent, we saw that that base was at least three. It could be more than three, but it had to be at least three. And that stem portion, in our view, is supported by looking at the examples they gave us in -- in the record.

Okay. Now, let's go back to Slide 35, I guess.

Now, it is true that the specification does not define the number of basepairs. However, our view is that in order to have a proper structure, you've got to have at least three basepairs. If you've got less than that, it's not going to be a proper structure.

Next slide.

Now, we point to their examples. You see Figure 4, again, you see the -- the three lines, or in one case four, those are basepairs. Those are connected together.

In their -- in their definition during the prosecution, they said a hairpin consists of a basepair double-helical region, the stem, with a loop of unpaired bases at one end. And, again, you see the stem. That's why in our view, our definition requiring the three basepairs is important, but the most important thing is it cannot be a probe.

Next slide.

All right. Now, I suppose people can argue about everything, but here our position is very clear. In the argument -- in the -- in their disclosure where they say A1 to A7, the math is very simple. They count -- go to the next slide -- you've got to count the nucleotides. So you start with your reporter, then you go to the quencher. Their examples in our view all support that, and there's no example where you exclude the reporter and include the quencher, which is what they are proposing.

Obviously, if you do the math, and it's supposed to be 15 nucleotides apart, it works for us. It doesn't work if you exclude the reporter, and then you're left with -- with just 14.

Next slide.

Terminal nucleotide. Why is that important? That's important because when you look at the specifications for the '591, as well as for the '848 --

THE COURT: Well, let me go back to the previous term.

MR. JOHNSON: Yes.

THE COURT: I mean, you agree that the prosecution history example shows something different from what you're arguing?

MR. JOHNSON: I -- I've got to see that example and have it in front of me. I don't...

Do we have that -- let me grab their slides and look at them.

I think we're at Page 32 of their slide, Your Honor.

THE COURT: I was on Page 18 of their brief, but...

MR. JOHNSON: So their slide, which is what I think it is, yeah.

THE COURT: Yes.

MR. JOHNSON: Yeah, and in that scenario, they, in fact, are counting both, as I understand it. They say they are separated by seven, but if you do the math, it's one, two, three, four, five, six, seven, in the eighth one, the E is the quencher.

THE COURT: Correct. So they don't count the reporter, but they do count the quencher?

MR. JOHNSON: Well, or they -- either that, or they count the -- the reporter but don't count the quencher. I mean, there's no way you can tell from this.

THE COURT: But in any event, it's separated by seven nucleotides?

MR. JOHNSON: Correct.

THE COURT: Okay. And so, I mean, my question is this is different from what you're arguing, correct?

MR. JOHNSON: That is correct.

Now, the term terminal nucleotide, as I pointed out, as I was about to say, is in both of the two primary patents, in the first '848 -- in the '848, the language refers to the importance of having a term -- the attachment at the terminal, and the reason it's important, according to -- to the claim, is if you have an internal attachment, that creates problems you don't want. So that's -- this is what started it.

If you go back to the '848. If you want, I can get you the specific language, Your Honor. If you look at -- if you look at Column 5 of the '848, and if you go down to Lines 37 through 43, it says, preferably, the three prime terminal nucleotide of the oligonucleotide probe is blocked or rendered incapable of extension by a nucleotide -- a nucleic acid polymerase. Such blocking is conveniently carried out by the attachment of a reporter or quencher molecule to the terminal three carbon of the oligonucleotide probe by a linking moiety.

In the '591, they say the same thing except they call it an attachment to the terminal nucleotide.

So the reason terminal nucleotide or terminal carbon is important is they make it very clear that if you don't want to attach it to internally, you want to attach -- attach it at the terminal.

So now what is the terminal either nucleotide or carbon? Our view of the world is that in order for this jury to have an understanding, it's got to be defined because there are lots of things on those ends of the -- of these particular strings that need to be defined.

Our -- and so that's why we defined it to include a base, a ribose with deoxyribose structure and phosphate or modified phosphate structure.

Plaintiffs then said, well, but you have to include ribose or deoxyribose structures. We don't care. We -- but if you don't define it this way and if you just say it's a terminal nucleotide, you say too much, because, in fact, there are specific end points. It's either going -- you call it a carbon, you're going to be looking at these things.

What we've done here is try to make it clear what is at that terminal point. And that's all we're trying to accomplish here. We don't believe the notion that it -- it doesn't have -- it's entitled to its plain and ordinary meaning makes a lot of sense.

Now, we get to the factor six. The problem with their argument is they spend all the time saying that, well, the oligonucleotide has a structure. And so, therefore, it's been disclosed. The problem with their argument is the issue is how do you figure out the ratio of the fluorescence of said reporter molecule and said quencher molecule when the probe is hybridized to a target polynucleotide, okay? And it's got to be, according to their -- to their claim, a factor of six.

So I've got to know -- first, I've got to be able to measure it and I have to be able to develop a protocol that results in at least a factor of six difference in intensity or I don't practice the patent.

How do I do that? Short answer is there's no way one can tell looking at the language of these claims. That's why we argue they have to be means-plus-function because they don't disclose sufficient detail to enable someone of ordinary skill in the art how to practice this invention. The only place in the patent that does is the previously-quoted recipe.

If they -- and if -- the argument that, well, you have a structure, you know it's an oligonucleotide. As we pointed out, an oligonucleotide can be all sorts of things, but more than that, you have to figure out how to get to this -- this ratio --

fluorescence ratio. You can't do it without more information, and that is the essence of our argument across the board.

This alone cannot be sufficient, that, in fact, you called it a method in the patent, if you look at the '591 again, Columns 18 and 19, you will see specifically they called it their method, and then they give you their recipe. Without the recipe, nobody can figure this out unless you make the assumption that, oh, it's obvious. Well, if it was obvious, why would you have to know the exact amount of magnesium, the exact temperature, and the exact cycle base in order to -- in order to determine what the appropriate level of fluorescence is?

It's the same argument for all of them, Your Honor. If we're right and you have to have a recipe, then we're correct, and it's -- it then becomes means-plus-function. If it's not a recipe, then it's indefinite because you cannot figure out how in the world to do this.

If you remember -- if we go back to the earlier slide where we had the recipe up, and let's go to the next slide here, here is Column 19, No. 5, it is headed, and this is in every one of the patents. This is the same recipe. Method for monitoring PCR

amplifications using oligonucleotide probe. This is the method they disclosed, and you have to know what the magnesium concentration is. Instead of making it four, if you made it eight, what happens? If you make it 80 cycles, what happens? If you change the degree, you change the result.

I don't know how you can do it otherwise. It's a bit like saying, I can make you an apple pie without giving you any information about how to do it and assume that, oh, well, you know, you know what apples are, you'll figure it out. That is, in essence, what they're saying.

That cannot be right, and if it was right, you wouldn't need to have this much detail covering all of their critical parameters in order to get to this hope for greater than six. That's all -- all I have, Your Honor.

THE COURT: Okay. Thank you.

Any rebuttal?

MR. MALONEY: We do, Your Honor.

THE COURT: Just -- before you get up there, I don't allow sur-rebuttal, so take your shots now. Don't be holding back.

MR. JOHNSON: I understand, Your Honor.

THE COURT: All right.

MR. JOHNSON: I didn't think you would give me another shot, but I'll take it if you let me have it.

THE COURT: I just historically have not allowed sur-rebuttals.

MR. JOHNSON: That's all right.

MR. MALONEY: If we could have just a small -- small break.

THE COURT: Why don't we take 10 minutes. We'll come back and hear the rest of the arguments. Back in 15 is fine.

MR. MALONEY: Okay.

MR. JOHNSON: All right.

LAW CLERK: All rise.

(Recess.)

LAW CLERK: All rise.

THE COURT: Please be seated.

All right. Rebuttal?

MS. SCHMID: Thank you, Your Honor.

Your Honor, I'll walk through each of the terms in the same order we discussed them before. I'll begin with the term quencher molecule.

If I could have Slide 6.

Defendant's argument regarding quencher molecule relies on part of the prosecution history that discusses substantially quenched. But they're confusing

the idea of quenching with the idea of emission. So you may remember, this is a quencher molecule. This is a fluorescent quencher molecule on top. It does two things. One is it absorbs the fluorescence from the reporter. That's the process that's called quenching. The second thing it can do but doesn't have to do is emit light. We know this because a dark quencher absorbs light from the reporter. It's still a quencher. It's still quenching the reporter, quenching the signal that comes from the reporter.

So when the patentees were discussing with the Patent Office whether or not these quencher molecules substantially quench, what they're talking about is this red line. Does all of that red line go to the blue line? However what we're debating in construction is this blue line. Are both of these quenchers are only the ones that are fluorescent quencher (sic).

But as Defendants themselves define, this dark quencher is still a quencher, and as we discussed earlier, the intrinsic record is very clear. The -- the patentees know how to claim a fluorescent quencher when they want to, but they don't always claim it. Sometimes they just claim a quencher molecule.

They in the specification multiple times say

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fluorescence -- quenchers can be fluorescent or they can be nonfluorescent. The fact that some of the claims use a ratio that has the emission of the quencher on the bottom, yes, it means that those particular claims cannot include a quencher where the emission is 0.

It is worth noting that even some quenchers that are called dark quenchers, the emission may just be very, very low and may not actually be 0. So those kinds of quenchers just because dark was in their name would not be excluded from those claims. But regardless, there's a variety of ratio claims in the patent. Some of them involve quencher fluorescence, but many of them don't. Some of them are just talking about reporter -- reporter fluorescence.

The patentees knew how to use the words they wanted to use, they used the words they wanted to do, and ultimately, if the Court disagrees, perhaps some of the claims are invalid, but given how clear the intrinsic record is, the Court should not try to save the patentees from themselves and try to, in order to preserve the validity of certain claims, ignore what the entire intrinsic record has said about quencher molecule.

THE COURT: Well, what claims would not be at risk?

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MS. SCHMID: The majority of them. Essentially, it is one claim that has this term at issue. I believe it is Claim 24 of the '848 patent.

In later patents --

THE COURT: I'm sorry, tell me that again.

MS. SCHMID: Claim 24 of the '848 patent includes the ratio.

While there are other claims in later patents that discuss a ratio, each of those requires a fluorescent quencher.

THE COURT: Okay.

MS. SCHMID: This is the only one that has the quencher on the bottom.

THE COURT: Your validity argument is that it wouldn't -- those claims that require comparisons would not be at risk because they don't require a ratio as -- as the comparison?

MS. SCHMID: The only -- the only claims that would be at risk, if -- if there is this dark quencher, would be a claim that specifically has emission of the quencher on the bottom of a -- of a ratio, and that's pretty much the only one that doesn't --

THE COURT: Right. Okay.

MS. SCHMID: -- limit it to a fluorescent

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quencher.

Bottom line, the reason that Defendants are arguing this, they are very -- while they say this is about preserving validity, they haven't raised that point with any of the other claims. What this is really about, it's them trying to get some of their infringing products off the hook.

Their main -- one of the main quenchers they use is called BHQ, which stands for black hole quencher, so what they want to do is say, hey, by the fact that we're using BHQ, we want to get off the hook for infringing your claims.

So as much as Defendants are purporting to care about the validity of -- of Plaintiffs' -- of Plaintiffs' patents, really what this is about is non-infringement.

The next term is hairpin structure. Now, I'm going to switch to the ELMO, I believe. And Defendants here showed some discussion with the Patent Office from Exhibit G. I'm going to try and put the same thing up. And as part of this, this is the part of the prosecution history -- I'm on Exhibit G. What the applicant said is the intention of applicants to exclude probes which are designed to form hairpin structures.

Defendants argue that what applicants are

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doing here is saying that hairpin structures cannot be probes as we defined hairpin structures, but that's misreading the context of what's going on here. Remember, when we looked at the claim earlier, we saw that hairpin structure is a negative limitation. The patentees are saying, we're claiming probes unless they form a hairpin structure. And the reason is a particular kind of prior art called molecular -- molecular beacons.

Now, as the Court may have determined from the briefing, what these patents are about is a certain kind of probe and about the relationship of the reporter and quencher. Prior to these patents, there was a structure called the molecular beacon structure which used a hairpin structure to bring a reporter and a quencher next to each other, but this patent was the first time that people found a way to have probes that had the reporter and quencher together without that hairpin structure, which is why in the claims there's the negative limitations saying, our probes are probes that do not form this hairpin structure, which is exactly what they're explaining to the examiner here.

The intention of applicants is to exclude those probes that are designed to form a hairpin structure. So far from saying that hairpins cannot be

probes, what this is saying is the type of hairpins we're talking about here are probes. They're the probes which form hairpin structures. That's exactly what the examiner and the patentees are talking about, which is why the Defendant's construction, which ignores the reporter and quencher, cannot be right. The intrinsic evidence is full of examples that what hairpin structures are talking about is bringing the reporter and quencher together.

Defendants argue that a hairpin must have at least three basepairs in the stem, and they show some examples from -- from the intrinsic record. We don't disagree that that's part of the plain and ordinary meaning of hairpin, and certainly if the Court believes that that would provide further clarification for a jury, just as we're asking the Court to provide clarification about the meaning of proximity, we would not be opposed to including in addition to the relationship of the reporter and quencher that the stem must include at least three basepairs.

But what the intrinsic record is extremely clear about is that a hairpin structure is not necessarily just a general hairpin structure of any sequence of DNA. It's about a probe that's folding back on itself to bring a reporter and quencher together.

The next term is the term relating to separation of reporter and quencher molecules. Defendant's only argument is the plain and ordinary meaning. Given that there's a definition in the specification which is applied in the prosecution history, this is the definition the Court should adopt.

On terminal nucleotide, still, the Defendants are using the word of the term in their proposed construction. Plaintiffs believe no construction is -- is needed. If, in fact, the Court decides a construction is needed, Plaintiffs provided the plain and ordinary meaning based on the intrinsic record.

Turning to the monitoring the fluorescence, now, an analogy that Plaintiffs (sic) used relating to the later terms, the factor of six, that applies throughout is this idea of the apple pie, that you need very specific instructions to be able to make an apple pie.

MR. JOHNSON: That was my analogy.

MS. SCHMID: I'm sorry.

MR. JOHNSON: You said, Plaintiffs.

MS. SCHMID: I said, Plaintiffs. I'm so sorry, the Defendants.

Now, while this may be very true for someone

like me who's not good at baking, I certainly need pretty specific instructions. For one of skill in the art of cooking, you can certainly go to a chef and say, I'd like an apple pie, and they know how to make an apple pie. You can say, I'd like an apple pie with a lattice crust, and they can make that kind of apple pie.

And that's what monitoring the fluorescence is like. Defendants have argued that people didn't know how to monitor fluorescence, but this is pure attorney argument. They've submitted no expert declaration. Quite to the contrary, the -- the two references that Plaintiffs described, the Higuchi references, both clearly described in a scientific journal exact steps that they took to monitor fluorescence. One of skill in the art could read those papers and apply the techniques taught in those two papers.

Finally, the last three terms relating to optimization. Again, while Defendants are arguing that one of skill in the art would have needed an exact recipe, they're offering only attorney argument for this proposition.

However, Defendants -- Plaintiffs have offered evidence that, in fact, skilled artisans knew how to optimize conditions.

If we go to Slide 65.

Plaintiffs have cited two pieces of art showing PCR buffer optimization, different optimizations. Skilled artisans knew what PCR reactions were. They were invented long before these patents were filed, knew how -- what the different factors were that impacted them. Knew how to do tests to figure out which conditions worked for which reactions. To the extent my answer to the Court's question was confusing before, I would like to clarify.

THE COURT: It's probably a product of the Court's question being confusing as opposed to your answer.

MS. SCHMID: My answer may have been confusing, so to make sure we're on the same page, what I intended to say was the test for this, it's simple. A skilled artisan would optimize a PCR reaction as they knew how to do very, very well, and at that point, fluorescence readings would be taken, and it's a yes or no question. Does it meet this ratio?

So going back and trying to tinker with the ratio saying, oh, I didn't like that result, let me try again, and going outside of that optimized range, that would not infringe the patent.

THE COURT: Has the method of optimization in the art changed from 1994 until today?

MS. SCHMID: I'm not sure, but it certainly could be at the time these patents were filed is the optimization that would apply.

THE COURT: And that's -- I mean, that's kind of what I was driving at, although inartfully, is unless we know under which conditions the measurements are to be taken, how does one know whether the comparison or the -- the products that are yielded by the tests are those that are involved in the claims so that we can determine infringement or non-infringement?

MS. SCHMID: Yes. The optimization as it would have been applied at the time of filing is the optimization that would apply.

THE COURT: Okay. I mean, I agree with that proposition, I just didn't know if we needed to make it clear so that there's -- there's not any debate on down the road as to which optimization is the accurate.

MS. SCHMID: And if there are no further questions from the Court, the Plaintiffs thank the Court for his time.

THE COURT: I'm not going to try that again.

MS. SCHMID: Oh, I guess in summary -- oh, no, actually, two -- I'm so sorry. I have two slides.

One of which is Defendants also reiterated

several times that the conditions have to come from the single example in the patent.

Switching back to the ELMO.

THE COURT: The dark quencher.

MS. SCHMID: It is. Does anyone know how I turn it to a light quencher?

Okay. So Phillips already considered that argument and rejected it stating, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. Instead the test is what one of ordinary skill in the art would have understood at the time.

In summary -- one other quick point before I summarize. Just to reemphasize on the term hairpin structure, as discussed, there is an express definition given in the record, and as we explained throughout the intrinsic record, there's an emphasis that what the patentees are really talking about is bringing the reporter and quencher together.

This Court expressed some skepticism about the clarification of proximity as "next to." The word "together" expresses that just as well, and it's the same word that the patent examiner used, but really got at the idea of why is this limitation in there, what is

this -- this word about, and what kinds of prior art were the patentees and the examiners talking about?

So in conclusion, Your Honor has heard two different approaches to claim construction today. The Plaintiffs described using definitions of claim terms in the specification where they're provided, using the plain and ordinary meaning of words, and applying controlling law. For example, looking at the law on means-plus-function and likewise looking at the law on applying definitions from Phillips.

And, similarly, the Courts cannot rewrite claims to preserve their validity. Defendants, on the other hand, are ignoring definitions from the specification, they're ignoring plain and ordinary meanings, and instead they're setting up complex self-serving rules to set up some undisclosed invalidity or non-infringement arguments.

For these reasons, the Plaintiffs ask the Court to adopt its constructions.

Thank you, Your Honor.

THE COURT: All right. Thank you.

I'll get you an order out. It will be -- I think I can get one out to you fairly quickly. Are there any other matters that we need to take up, case management, while I've got you here? Anything that

y'all know --

MR. JOHNSON: None, Your Honor.

MR. MALONEY: None from our perspective, Your Honor.

THE COURT: Okay. I just -- since I had y'all here, I'd rather, if there's any problems, try to deal with them today as opposed to --

MS. SCHMID: One order, the parties have been discussing a possible modification to the scheduling order. Currently expert reports are due 30 days after the issue of claim construction ruling, and the parties are discussing stipulating to a later date since discovery doesn't close until early summer. However, the parties have not yet agreed on a specific date, so that will be submitted later.

THE COURT: If you can agree to a date, submit an agreed order and I'll sign it.

MS. SCHMID: Thank you, Your Honor.

THE COURT: If there's a dispute about it, you know, file a motion and I'll probably try to deal with it on the papers as opposed to having any kind of hearing. If I do a hearing, I'd probably do it telephonically just so that I can -- if there is anything that wasn't fully vetted in the papers. I would suspect that would be the type of thing y'all can

resolve by agreement, okay?
MR. JOHNSON: Thank you, Your Honor.
THE COURT: Thank y'all.
LAW CLERK: All rise.
THE COURT: Y'all travel safely.
MR. JOHNSON: All right.
MR. HAWES: Thank you, Your Honor.
(Recess.)

CERTIFICATION

I HEREBY CERTIFY that the foregoing is a true and correct transcript from the stenographic notes of the proceedings in the above-entitled matter to the best of my ability.

SHELLY HOLMES Date
Deputy Official Reporter
State of Texas No.: 7804
Expiration Date: 12/31/12